Remarks

Applicants have amended claim 2 to add a sequence identifier. Support for the SEQ ID NO may be found in the Sequence Listing submitted on June 13, 2002.

Applicants have amended claims 9 and 13 to respond to the Examiner's rejections. Specifically, applicants have replaced the term "multiple antigen peptide" in claim 9 with "multiple-antigen peptide (MAP)" according to the Examiner's suggestion. Support for these amendments is found, e.g., at page 20, line 11. Applicants have also replaced recitation of "the characteristics of HB 11311" in claim 13 with "the specific immunological reactivity of HB 11311" according to the Examiner's suggestion. Support for these amendments is found, e.g., at page 26, lines 19-25.

Applicants have also amended claims 12 and 13 to depend from claim 1. Support for these amendments is found, e.g., at page 18, line 12 to page 19, line 27.

Applicants have canceled claims 11 and 14 without prejudice. Applicants expressly reserve the right to pursue the canceled subject matter in applications that claim benefit from this application.

Applicants have amended claim 15 to remove dependencies from canceled claims.

Applicants submit that these amendments place the claims in condition for allowance or at least present the rejected claims in better form for consideration on appeal and should therefore be entered after the final rejection. 37 C.F.R. § 1.116(a).

The above amendments to the claims do not narrow the claims in any way. No new matter has been added.

The Objections

Regarding the objection to the drawings made in paragraph 7 and set forth in Form PTO 948, applicants will submit formal drawings upon receipt of the Notice of Allowability, as set forth in 37 C.F.R. § 1.85.

The Rejections

Double Patenting

The Examiner has maintained the rejection of claims 1, 3, and 9-15 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-3 and 6 of U.S. Patent No. 5,476,784, claims 1-9 and 11 of U.S. Patent No. 5,939,067, and claims 1-4 of U.S. Patent No. 6,099,839. Applicants traverse.

As discussed in detail below, applicants' amended claims are not anticipated by any of the claims from the '784, '067, and '839 patents cited by the Examiner. Nor are any of the amended claims obvious in view of the cited claims. Applicants' claims are directed to peptide mimics that are capable of inducing an immune response. In contrast, the cited prior art only describes anti-idiotypic antibody fragments that may retain the binding specificity of the parent antibody. No fragments are exemplified in the three cited patents. Nowhere do any of the cited references describe or suggest fragments capable of inducing an immune response. A

bare discussion of antibody fragments that may bind to a conserved gonococcal epitope does not confer upon one of skill in the art a reasonable expectation of successfully achieving the presently claimed immune response Accordingly, this rejection may properly be withdrawn.

35 U.S.C. § 112, second paragraph

The Examiner has maintained the rejection of claims 2, 4-10, and 13-15 under 35 U.S.C. § 112, second paragraph as allegedly being indefinite and failing to distinctly claim the subject matter which applicant regards as the invention. The specific rejections are discussed below.

(a) The Examiner asserts that claim 13 is indefinite for reciting "the characteristics of HB 11311," and suggests replacing it with "the specific immunological reactivity of HB 11311." Applicants have amended this claim accordingly, thus, obviating this rejection.

(b) The Examiner contends that claims 9 and 14 are indefinite for reciting "multiple antigen peptide," and suggests replacing it with "multiple-antigen peptide (MAP)." Applicants have amended claim 9 accordingly and have canceled claim 14, thereby obviating the rejection of these claims.

(c) The Examiner alleges that claim 2 is indefinite for reciting "DE_GLF" because it is not clear what is meant by "_." Applicants have amended claim 2 to indicate that the

sequence "DE_GLF" refers to SEQ ID NO: 8. The Sequence Listing makes clear that "_" refers to any amino acid residue.

(d) The Examiner asserts that claim 6 is indefinite for reciting the term "tail" because it is not clear what is encompassed by this term. Applicants respectfully traverse.

Because the inventor is permitted to define the claim terms in the specification, applicants believe that one of skill in the art would understand "tail" to refer to what is described at page 19, lines 23-27. Thus, the term "tail" would be understood by the skilled artisan, in the context of this application, to refer to any structure that facilitates coupling of a peptide mimic to a second agent such as an adjuvant or carrier protein.

(e) The Examiner has maintained the rejection of claims 4-10 and 15 for being indefinite because they depend, directly or indirectly, from an indefinite base claim. Applicants believe they have clarified the base claims from which claims 4-10 and 15 depend, thereby obviating this rejection.

For all the above reasons, applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112, second paragraph rejections.

35 U.S.C. § 102

The Examiner has maintained the rejection of claims 1, 3, and 9-15 under 35 U.S.C. § 102(e) as allegedly being anticipated by the '839 patent, under 35 U.S.C. § 102(e) or

102(a) as being anticipated by the '067 patent, and under 35 U.S.C. § 102(b) as being anticipated by the '784 patent. Specifically, the Examiner alleges that the anti-idiotypic antibody fragments described in the '839, '067 and '784 patents anticipate applicants' peptide mimic of the rejected claims. The Examiner states that the application describes that a peptide mimic is a "peptide which exhibits an immunological antibody binding profile similar to that of a known epitope," and that the application does not exclude antibody fragments from the scope of "peptide mimic." The Examiner further states that in the absence of a specific closed definition in the specification, that a limitation is to be given a reasonably broad interpretation. The Examiner alleges that a review of the art indicates that antibodies and antibody fragments having the binding portion are recognized as peptide mimics. The Examiner concludes that the prior art antibody fragments inherently qualify as "peptide mimics" because they have the immunological specificity of the parent antibody. Finally, the Examiner contends that although the claimed product was obtained by a different process than the prior art antibody fragments, that applicants have not shown that the prior art product is structurally different from that of the claimed product. Applicants respectfully traverse.

Applicants have canceled claims 11 and 14, thereby obviating the rejection of this claim. As amended, claims 3, 9, 10, 12, 13, and 15 all depend from claim 1, which is directed to a peptide mimic of a conserved gonococcal epitope not found in human blood group antigens, wherein the peptide mimic is capable of inducing in a mammal an immune response against said conserved gonococcal epitope. Anticipation of a claim requires that the prior art reference teach every element of the claim. Here, the Examiner alleges that the anti-idiotypic

antibody fragments disclosed in the '839, '067, and '784 patents are encompassed by the claimed "peptide mimic" as defined in the application in connection with what is understood in the art. However, claim 1 is not directed simply to a peptide mimic but to a peptide mimic that is capable of inducing in a mammal an immune response against a conserved gonococcal epitope. None of the cited references teach anti-idiotypic antibody fragments that are capable of inducing such an immune response. The prior art fragments are defined to "retain the antigen binding specificity of the parent antibody." It says nothing about the capability of the fragments to induce an immune response. Furthermore, binding to an epitope does not necessarily result in induction of an immune response, thus, the prior art fragments do not inherently possess this capability. Accordingly, each of the '839, '067 and '784 patents fail to teach every element of the claimed invention.

In addition, none of the cited patents render obvious applicants' amended claims. Nowhere do any of the '839, '067 or '784 patents disclose or suggest peptide mimics that are capable of inducing an immune response to a conserved gonococcal epitope. The prior art fragments described in the cited references are asserted to have certain binding capabilities but none are exemplified, and none are demonstrated to be capable of eliciting an immune response. Even if one of skill in the art were motivated to create a claimed peptide mimic based on this prior art, they would have no reasonable expectation that a given antibody fragment would successfully elicit the required immune response. For these reasons this rejection may properly be withdrawn.

CONCLUSION

In view of the foregoing remarks, applicants request that the Examiner favorably reconsider this application and allow the claims pending herein. If the Examiner believes that a telephone conference would expedite allowance of this application, she is invited to telephone the undersigned at any time.

Respectfully submitted,

Margaret A. Pierri (Reg. No. 30,709)
S. Craig Rochester (Reg. No. 43,052)
Attorneys for Applicants
R. Minako Pazdera (Reg. No. 46,984)
Agent for Applicants
c/o FISH & NEAVE (Customer No. 1473)
1251 Avenue of the Americas
New York, New York 10020
Tel.: (212) 596-9000
Fax.: (212) 596-9090